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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,178	08/09/2001	Vladimir Bakhtashvili	#627-A	6379

7590 10/22/2002  
Albert Wai-Kit Chan  
Attorney at Law  
Suite 604  
141-07 20th Ave.  
Whitestone, NY 11357

EXAMINER

DAVIS, RUTH A

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/22/2002 10

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>		
	09/928,178		BAKHUTASHVILI, VLADIMIR		
	<b>Examiner</b>		<b>Art Unit</b>		
	Ruth A. Davis		1651		

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on 30 July 2002.

2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 1-10, 83 and 84 is/are pending in the application.

    4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 83 and 84 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All   b) ☐ Some \* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> .	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other:
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## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group II, claims 83 – 84 in Paper No. 9 is acknowledged. However, applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Objections***

2. Claims 83 – 84 are objected to because the claims depend on a cancelled claim.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 83 – 84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 83 – 84 are drawn to methods for protecting against Tumor Necrosis Factor (TNF), however are rendered vague and indefinite because they depend from a cancelled claim. Moreover, it is unclear what composition is contacted and/or administered in the methods.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

6. Claims 83 – 84 are rejected under 35 U.S.C. 102(b) as being anticipated by Zetter et al. (WO 97/11691).

Applicant claims a method for protecting against the effects of TNF in a cell, the method comprising contacting the cell with an effective amount of a composition obtainable from human amniotic tissue that has apoptosis modulating activity. Applicant claims a method for protecting against the effects of TNF in a subject, the method comprising administering to the subject an effective amount of a composition obtainable from human amniotic tissue that has apoptosis modulating activity.

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Zetter et al. teaches a method for inducing cell apoptosis, the method comprising contacting a cell with an effective amount of spermine (p.4, line 19-21). Zetter additionally teaches a method for treating benign prostate hyperplasia in a human, the method comprising administering to the human an effective amount of spermine (p. 4, line 25-27).

At the time of the claimed invention, it was well known in the art that spermine is obtainable from human amniotic tissue (see Tracey et al., US 6011005, col.1 line 20-25). As evidenced by Zetter, spermine also has apoptosis modulating activity. As such, by practicing the methods of Zetter, administering spermine, a composition obtainable from human amniotic tissue with apoptosis modulating activity, to a cell or subject, one would inherently be protecting against TNF. Moreover, although Zetter does not teach the method for protecting against the effects of TNF, the method steps are the same. Therefore, by practicing the method of Zetter, one in the art would inherently be protecting against the effects of TNF as claimed.

Therefore the reference anticipates the claimed subject matter.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 83 – 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tracey et al. (US 6011005).

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Applicant claims a method for protecting against the effects of TNF in a cell, the method comprising contacting the cell with an effective amount of a composition obtainable from human amniotic tissue that has apoptosis modulating activity. Applicant claims a method for protecting against the effects of TNF in a subject, the method comprising administering to the subject an effective amount of a composition obtainable from human amniotic tissue that has apoptosis modulating activity.

Tracey teaches that spermine is obtainable from the amnion and inhibits the production of TNF (or protects against the effects of TNF) (col.1 line 20-25).

Tracey does not specifically teach a method for protecting against the effects of TNF in a cell or subject wherein spermine is administered. However, Tracey does teach that spermine is ideal for counter regulating TNF production. At the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to use spermine in a method for protecting against effects of TNF, since Tracey teaches the composition exhibits the claimed activity. Although the reference does not teach that spermine modulates apoptosis activity, such attributes are inherent to the spermine. In support, Zetter teaches that spermine induces (or modulates) cell apoptosis (see WO 97/11691, page 4). Therefore, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Tracey to administer spermine (a composition obtainable from human amniotic tissue with apoptosis modulating activity) to a cell or subject, with a reasonable expectation for successfully protecting against the effects of TNF.

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9. Claims 83 – 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cialdi et al. (6051701).

Applicant claims a method for protecting against the effects of TNF in a cell, the method comprising contacting the cell with an effective amount of a composition obtainable from human amniotic tissue that has apoptosis modulating activity. Applicant claims a method for protecting against the effects of TNF in a subject, the method comprising administering to the subject an effective amount of a composition obtainable from human amniotic tissue that has apoptosis modulating activity.

Cialdi et al. teaches that hyaluronic acid (HA) inhibits the production of tumor necrosis factor and can be used to treat TNF-mediated inflammation, systemic toxicology and related pathologies (col.3 line 53-60, example 16).

Cialdi does not specifically teach a method for protecting against the effects of TNF in a cell or subject wherein HA is administered. However, Cialdi does teach that HA can be used for treating TNF mediated inflammation and related pathologies. At the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to use the HA of Cialdi in a method for protecting against effects of TNF, since Cialdi teaches is exhibits the activity as claimed. Although the reference does not teach that HA is obtainable from amniotic tissue or modulates apoptosis activity, such attributes were known at the time of the claimed invention. In support, Wang et al. (US 5932205) teaches that HA is a major component of amniotic tissues (col.6 line 46-51) and Kaneko et al. (March 2000, J. Ass. Reprod. And Gen.) teaches that hyaluronic acid inhibits (or modulates) cell apoptosis (abstract). Therefore, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by

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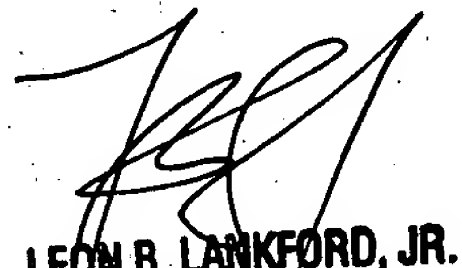
Cialdi to administer HA (a composition obtainable from human amniotic tissue with apoptosis modulating activity) to a cell or subject, with a reasonable expectation for successfully protecting against the effects of TNF.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad  
October 17, 2002

  
LEON B. LANKFORD, JR.  
PRIMARY EXAMINER